K132585

JUN 04 2014

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date of preparation: **June 4, 2014**

1.	**Submitter's Name:**	**Coho Technology Co., Ltd.**
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	Contact:	Jacky Hsieh / Vice General Manager
2. Device Name :		
	Trade Name:	Zibone Ceramic Dental Implant System
	Common Name:	Endosseous dental implant
	Classification name	Implant, Endosseous, Root-Form
3. Device Class:		**Zibone Ceramic Dental Implant System has been classified as** Regulatory Class: II Product Code: DZE Panel : Dental Regulation Number: 21CFR 872.3640
4. Predicate Device:		The predicate device is the • **Z-Systems AG** – Z-Look3 Dental Implant System – (K062542) marketed byZ-Look3 dental implant system
5. Indications for Use		**"Zibone one-piece ceramic dental implants are indicated for implantation into the upper or lower jaw to replace missing teeth. They are indicated for (delayed or immediate) loading once primary stability has been achieved."**
6. Device Description:		Zibone ® Ceramic (Zirconia) Dental Implants are threaded; root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices. The implants are manufactured from **yttrium stabilized zirconium oxide bioceramics material**

conforming to ISO 13356-2008: Implants for surgery-ceramic materials based on yttria-stablized tetragonal ziconia (Y-TZP). The implant has a **one-piece design** (both implant and abutment), which simplifies the surgical procedures.

The implants are single use devices and are delivered in sterile condition have been sterilized with moisture heat. Zibone ceramic dental implants are also subjected to a sandblasting process that is used to impart the surface of the devices to enhance the osseointegration process.

Zibone dental implants are offered in three diameters (3.6mm, 4mm and 5mm) and 5 insertion lengths (8mm, 10mm, 11.5mm, 13mm and 14.5mm) for different teeth. The general rule is to select largest and longest implant size that the indication permits.

7. **Substantial Equivalence:**

Item	Subject Device	Predicate Device
510(k) Number		K062542
FDA regulation no.	872.3640	872.3640
Device Name	Zibone ceramic dental implant system	Z-Look3 dental implant system
Manufacturer	Coho Tech Co., Ltd.	Z-Systems AG
Intended Use	To be surgically place in the upper or lower jaw to provide support for dental prosthetics and restore chewing functions.	Same
Device Configuration	Screw Type One-Piece; without the need to attach an abutment	Screw Type One-Piece; without the need to attach an abutment
Device Dimension	Diameter: 3.6, 4.0, 5.0mm Insertion length: 8, 10, 11.5mm, 13mm and 14.5mm	Diameter: 3.6, 4.0, 5.0mm Insertion length: 10mm, 11.5mm, 13mm and 14mm
Material Composition	Zirconium Oxide	Zirconium Oxide
Surface Treatment	Sandblast	Sandblast
Sterilization Method	Moisture Heat	Moisture Heat

Summary of substantial Equivalence Comparison

The Zibone Dental Implant System has the same device characteristics as the predicate device –Z-lock3 dental implant system (K062542), intended use, material, design, surface treatment, sterilization method. Even slight differences in design characteristics and dimension do not affect the submission of the device. Therefore, we state that Zibone Ceramic Dental Implant System is substantially equivalent to predicate device.

8. Summary of Nonclinical Testing:	The following were reviewed to support the performance of Zibone Ceramic Dental Implant System: Fatigue test to ISO 14801, Sterilization validation, Shelf life testing, Surface analysis & Biocompatibility testing.
9. Summary of Clinical Testing:	No Clinical studies are submitted.
10. Conclusions:	The **Zibone Ceramic Dental Implant System** has the same indication for use , the same basic designs and materials, the same surface treatment and the same sterilization method as the **Z-Look3 Dental Implant System (K062542)** marketed by. **Z-Systems AG.** Moreover, bench testing contained in this submission demonstrates that any differences do not raise any new questions of safety or effectiveness. Thus, the **Zibone Ceramic Dental Implant System** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 4, 2014

Coho Technology Company Limited
C/O Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 N. Boldt Drive
Flagstaff, AZ 86001

Re: K132585
Trade/Device Name: Zibone Ceramic Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseus Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 24, 2014
Received: May 5, 2014

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

003_Indications for Use Statement (C)

Indications for Use

510(k) Number (if known): K132585

Device Name: **Zibone Ceramic Dental Implant System**
COHO TECHNOLOGY CO., LTD.

Indications for use:

Zibone one-piece ceramic dental implants are indicated for implantation into the upper or lower jaw to replace missing teeth. They are indicated for (delayed or immediate) loading once primary stability has been achieved.

Prescription Use V AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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